Cont B1

--17. (new) The method according to claim 10, wherein the preparation is administered in an amount of between 10 and 100,000 international units (IU) per gram of dosage.

--18. (new) The method according to claim 10, wherein the preparation further contains an inhibitor of intestinal proteolytic enzymes.

--19. (new) The method according to claim 10, wherein the mammal is overweight or obese.--

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-8 have been cancelled and new claims 10-19 have been added. Support for new claims 10-19 may be found in original claims 1-8 and generally throughout the specification. Specifically, support for claim 15 may be found on page 11, lines 27-28. Support for claim 16 may be found on page 6, lines 26-27. Claim 17 is supported on page 7, lines 1-3. Beginning on page 8, support for claim 18 may be found. Support for claim 19 may be found on page 10, lines 2-3. Thus, it is respectfully submitted that no new matter has been added to the present application.

In the outstanding Official Action, claims 1, 2 and 4-8 were rejected under 35 USC §112, first paragraph, as allegedly

being based on a non-enabling disclosure. This rejection is respectfully traversed.

The outstanding Official Action alleged that while the present disclosure is enabled for glucose isomerase, the present disclosure is not enabling for any and all enzymes capable of converting an ingested carbohydrate or digestion product into one or more absorbable components. The Examiner's attention is respectfully directed to claims 10-19. Claims 10-19 are directed to administering to a mammal an effective amount of a preparation containing glucose isomerase. Thus, it is respectfully submitted that the claimed invention is based on a enabling disclosure.

Claims 1-8 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. This rejection is respectfully traversed.

It is respectfully submitted that claims 10-19 have been drafted in a manner that obviate the indefiniteness rejections of the outstanding Official Action. It is believed that the claims have been amended to remove any problems relating to antecedent basis. Moreover, the claims have been drafted in a manner so that the phrase "and/or" is no longer recited. Thus, it is believed that claims 10-19 are definite to one of ordinary skill in the art.

In the outstanding Official Action, claims 1, 2 and 5 were rejected under 35 USC §102(b) as allegedly being anticipated by SU 654682 (SU) or JP 408245397. This rejection is respectfully traversed.

The SU publication describes a bacterial strain that is used as a D-glucose isomerase producer. The glucose isomerase is described to be useful in the production of dietary fructose from glucose-containing syrups. In the industrial production of fructose from (corn) glucose syrups, glucose isomerase is immobilized, i.e., absorbed on a carrier.

The glucose isomerase-containing carriers are removed from the syrup prior to consumption, meaning that the resulting product is essentially free of glucose isomerase. Moreover, the SU publication clearly suggests that the fructose can be used by diabetic patients. The document does not disclose or suggest the enteral administration of glucose isomerase.

Furthermore, the SU publication is not concerned with a method for treating or preventing obesity, fluctuations in blood insulin levels and/or fluctuations in blood glucose levels. Hence, applicants respectfully submit that the SU publication fails to anticipate or render obvious the claimed invention.

The JP 408245397 publication describes the oral administration of an inhibitor of glucose-6-phosphate inhibitor for treating and inhibiting humectation and metastasis of a cancer cell. As noted above, the present invention is directed

to a method of treating or preventing obesity, being overweight, fluctuations in blood insulin levels or fluctuations in blood glucose levels. While the Official Action states that the JP 408245397 publication describes a glucose-6-phosphate isomerase, applicants respectfully submit that the abstract of JP 408245397 is rather ambiguous.

From the title of the patent and a machine assisted translation (see attachment) of the claims, it is apparent that the document describes the administration of a glucose-6-phosphate inhibitor, i.e., not of the isomerase itself. Hence, the document does not relate to the administration of glucose isomerase and therefore does not disclose or suggest the method defined in the claimed invention.

Applicants respectfully submit that the JP 408245397 and SU publications fail to disclose each and every recitation of the claimed invention. As the Examiner is aware, to constitute anticipation, all recitations must be found in one prior art source. *In re Marshall*, 577 F.2d 301, 198 USPQ 344 (CCPA 1978). As the cited publications fail to disclose each and every recitation, alone or even in combination with each other, applicants respectfully submit that the publications fail to anticipate or render obvious the claimed invention.

Claims 1-8 were rejected under 35 USC §103(a) as allegedly being unpatentable over SU 654682 (SU) or JP 408245397 (JP1) in view of TSUJINO 3,789,117 and JP 410287575 (JP2). This

rejection is respectfully traversed.

Applicants believe that there was no motivation or reasonable expectation of success for the skilled person to combine the cited references to obtain the claimed invention. The cited references relate to completely different technical fields: SU relates to catalyst production for industrial sugar processing; JP 408245397 (JP1) relates to the treatment of cancer using enzyme inhibitors; TSUJINO relates to the administration of acid liable drugs; and JP 410287575 (JP2) relates to the treatment of obesity, comprising the administration of enzyme inhibitors and sugar absorption inhibitors. Since the cited references do not relate to a similar technical field and do not deal with related issues, the combination of these references can only be deemed obvious with the benefit of hindsight. Applicants therefore respectfully traverse the obvious objection, since the skilled person, without any foreknowledge of the invention, would not seek to combine the cited references.

Furthermore, applicants respectfully disagree with the Official Action's contention that based on a combination of two or more of the references, the skilled artisan would arrive at the claimed invention. Since not one of the cited references describes or even suggests the enteral administration of glucose isomerase, it cannot be seen how the skilled person would arrive at this recitation of the claimed invention on the basis of the disclosure contained in these references.

As noted above, the SU publication merely relates to a Lactobacillus train that produces glucose isomerase. The glucose isomerase can be used as a catalyst in industrial fructose production. SU does not relate to the enteral administration of glucose isomerase. Hence, applicants respectfully disagree that SU can provide a suitable basis for an obvious rejection.

TSUJINO relates to medicaments that comprise an enteric coating, including coated medicaments containing enzymes. TSUJINO does not describe or suggest the use of glucose isomerase, nor does the document describe or suggest the use of enzymes in a method for the treatment or prevention of obesity, overweight, fluctuations in blood insulin levels and/or fluctuations in blood glucose levels in mammals.

The JP2 publication describes an antiobestic drug containing D-xylose (as an enzyme inhibitor) and a naturally occurring substance that inhibits the absorption of oligosaccharides and monosaccharides, e.g., Gymnema sylvestre. The JP2 publication does not describe or suggest the enteral administration of enzymes. In contrast, the JP2 publication suggests the use of enzyme inhibitors for the treatment of obesity. Hence, the JP2 publication actually teaches away from the claimed invention. Absent any hint in either SU, TSUJINO or JP2 towards a method comprising the enteral administration of glucose isomerase, and the lack of any suggestion to use glucose isomerase in a method for treating or preventing obesity,

fluctuations in blood insulin levels or fluctuations in blood glucose levels in mammals, the claimed invention cannot be obvious in view of these cited publications.

The JP1 publication relates to the use of an inhibitor of glucose-6-phosphate to treat cancer. Applicants' invention relate to a method of treating or preventing obesity, overweight, fluctuations in blood insulin levels and/or fluctuations in blood glucose levels, comprising the administration of glucose isomerase. Hence, applicants respectfully disagree that the JP1 publication can provide any basis for an obvious rejection.

Absent any hint in either JP1, TSUJINO or JP2 towards a method comprising enteral administration of glucose isomerase, and the lack of any suggestion to use glucose isomerase in a method for treating or preventing obesity, overweight, fluctuations in blood insulin levels and/or fluctuations in blood glucose levels in mammals, the claimed invention cannot be obvious in view of these references.

Claims 1-8 were rejected under 35 USC §103(a) as allegedly being unpatenatble over CAREY et al. 4,746,508 ('508) or CAREY et al. 4,959,358 ('358) in view of TSUJINO, SU, and JP 410287575 (JP2). This rejection is respectfully traversed.

Again, it is believed that there was no motivation for the skilled person to combine the cited references and that these references relate to completely different technical fields. CAREY et al. '508 and '358 relate to compositions and methods for

increasing drug permeability of body surfaces across which a drug is to be administered. TSUJINO relates to the field of acid liable drugs. SU relates to the field of catalyst production for industrial sugar processing. The JP2 publication relates to the treatment of obesity by administering enzyme inhibitors and sugar absorption inhibitors. Since the cited references do not relate to a similar or neighboring technical field and also do not deal with similar issues, the references may only be combined with the benefit of hindsight. Applicants therefore respectfully traverse the proposed obviousness rejection, since the skilled person, without any foreknowledge of the invention would not have any motivation to combine these references.

Furthermore, applicants respectfully disagree with the Official Action's opinion that based on a combination of two or more of the references, the skilled person would arrive at the claimed invention. None of the cited references describes or suggests enteral administration of glucose isomerase.

SU, JP2 and TSUJINO do not describe or suggest the enteral administration of glucose isomerase.

CAREY et al. '508 relate to a composition containing a drug and a biocompatible, water soluble amphiphilic steroid capable of increasing drug permeability of body surface across which the drug is administered. CAREY et al. '508 mention isomerases (column 9, line 26). However, CAREY et al. '508 do not describe, suggest or even mention glucose isomerase.

Furthermore, CAREY et al. '508 do not describe or suggest a method for the treatment or prevention of obesity, overweight, fluctuations in blood insulin levels and/or fluctuations in blood glucose levels in mammals.

CAREY et al. '508, TSUJINO, SU and JP2 do not teach or suggest a method comprising the enteral administration of glucose isomerase. Furthermore, the only reference that relates to the treatment of obesity (JP2), suggests the administration of an enzyme inhibitor. Hence, the claimed invention cannot be obvious in view of CAREY et al. '508, TSUJINO, SU and JP2.

SU, JP2 and TSUJINO do not describe or suggest the enteral administration of glucose isomerase.

CAREY et al. '358 relate to a composition containing a drug and a biocompatible, water soluble amphiphilic steroid capable of increasing drug permeability of body surface across which the drug is administered. CAREY et al. '358 mention isomerases (column 9, line 26). However, CAREY et al. '358 do not mention or suggest glucose isomerase. Furthermore, CAREY et al. '358 do not suggest the use of isomerases in a method for the treatment or prevention of obesity, fluctuations in blood insulin levels or fluctuations in blood glucose levels in mammals.

Absent any hint in CAREY et al. '358, TSUJINO, SU or JP2 towards a method comprising the enteral administration of glucose isomerase, the claimed invention cannot be obvious in view of these references.

The Official Action contends that it is known to administer glucose isomerase to patients to treat a condition. Applicants respectfully but strongly disagree with this view. In fact, not one of the above-cited references describes, teaches or suggest the enteral administration of glucose isomerase. Certainly, none of these references describes, teaches or suggest the enteral administration of glucose isomerase in a method of treating or preventing obesity, overweight, fluctuations in blood insulin levels or fluctuations in blood glucose levels in mammals. Thus, it is respectfully submitted that the cited publications alone or in combination with each other fail to render obvious the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 10-19, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

Respectfully submitted,

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